

## REMARKS

### ***Withdrawal of Enablement Rejection***

Applicants note with appreciation that the Examiner has withdrawn the rejection under 35 U.S.C. § 112 with respect to alleged lack of enablement. Specifically, the Examiner had alleged that “the specification ... does not reasonably provide enablement for *in vivo* extracellular administration that produces an intracellular biological response (such as modulation of protein expression)” (Office Action dated November 6, 2008, at page 3). The Examiner also had alleged that “[t]he specification does not enable any person skilled in the art ... to use the invention commensurate in scope with these claims” (*id.*).

By now withdrawing the rejection, the Examiner acknowledges that the specification ***does*** “reasonably provide enablement for *in vivo* extracellular administration that produces an intracellular biological response (such as modulation of protein expression),” and that the specification ***does*** “enable any person skilled in the art ... to use the invention commensurate in scope with these claims.”

### ***Priority***

The Office Action alleges that the pending claims are not entitled to the filing date of Application Serial No. 08/109591 because that application allegedly does not provide sufficient support for the claimed inventions. Applicants respectfully request that this decision regarding priority be reconsidered and withdrawn because it is plainly inconsistent with prosecution to date.

The Patent Office, for example, has already determined that the instant specification adequately supports each pending claim in accordance with 35 U.S.C. §112, first paragraph. Indeed, at no time have the claims been rejected for alleged lack of written description. Also, as noted above, an improvident rejection for alleged lack of enablement has been reconsidered and withdrawn.

The Patent Office’s determination that the instant specification supports the pending claims mandates that the Examiner reverse his position regarding entitlement to the filing date of Application Serial No. 08/109591. In this respect, Applicants note that the instant specification is substantively the same as that found in Application Serial No. 08/109591.

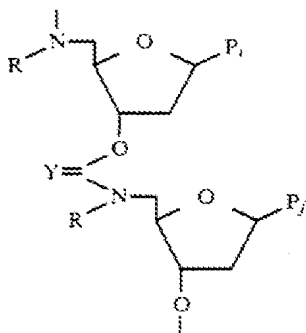
Since the disclosure of the instant specification provides adequate Section 112 support, it necessarily follows that the disclosure of the substantively same specification in Application Serial No. 08/109591 must also provide adequate Section 112 support and the priority benefit to Application Serial No. 08/109591 may be claimed. Accordingly, Applicants respectfully request that the denial of priority from Application Serial No. 08/109591 be reconsidered and withdrawn.

### *Alleged Anticipation*

Claims 34-36, 41, 48-51, 58, 59, and 65-68 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 5,142,047 (“the Summerton patent”). This rejection is improper because the Summerton patent is alleged to be relevant for its disclosure of compounds that have a different structure than those recited in the instant claims.

For a reference to be anticipatory, it must describe “all elements of [the] claimed invention arranged as in that claim.” *Carella v. Starlight Archery*, 804 F.2d 135, 138 (Fed. Cir. 1986); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1267 (Fed. Cir. 1991). Importantly, for a rejection to be proper under 35 U.S.C. § 102, the reference must “clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *In re Arkley*, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972) (emphasis in original).

The Summerton patent does not satisfy these requirements. The Examiner asserts that the linkages recited in the instant claims correspond to the linkage used in the following compound in the Summerton patent (Office Action dated November 6, 2008, at pages 8-10).



However, this linkage (*i.e.*, -**O**-C(=O)-NR- when Y is oxygen) is a carbamate linkage (a derivative of a carbonic acid), whereas the rejected claims recite an amide linkage (*i.e.*, -C-C(=O)-NR-) (a derivative of a carboxylic acid). Thus, there is no anticipation.

When Appellant brought this distinction to the Examiner's attention, the Examiner asserted that if one ignores the non-carbonyl oxygen atom in the -O-CO-NR- linkage, "the reference is viewed as containing the neutral amide linkage (underlined) as instantly claimed." (*id.* at pages 9-10). Such an interpretation, however, is not consistent with the understanding of a person skilled in the art. Those skilled in the art regard the "ignored" oxygen atom as integral to the structure of a carbamate group. Moreover, those skilled in the art would not simply ignore a functional atom in analyzing the linkage for various reasons, not the at least being the profound difference in electronic properties an oxygen atom verses a nitrogen atom verses a carbon atom have when position adjacent to the CO-NR- group. These differences in electronic properties are of fundamental importance to the nature of the group. A person skilled the art would not ignore the disputed oxygen atom (and view the remaining -CO-NR- portion of -O-CO-NR- as an amide) any more than they would also ignore the NR group (and view the remaining -O-CO- portion of -O-CO-NR- as an ester).

Additionally, in ignoring the oxygen atom of the Summerton structure the Examiner gives no indication of the fate of the pair of electrons that bond between the oxygen atom and the carbon atom of the carbonyl radical. If the pair of electrons are removed with the oxygen atom (after all oxygen is more electro negative that carbon) a carbocation results. Of course a carbocation has a net positive charge. A net positive charge is not neutral, as required by the claims at issue. If the pair of electrons is left with the carbon atom of the carbonyl group a carbanion results. Such carbanion has a net negative charge. A net negative charge is also not neutral as is required by the claims at issue.

The Summerton patent also refutes the Examiner's position that the oxygen atom can be ignored. The structure reproduced in the outstanding Office Action is found in column 5 of the Summerton patent, and is designated as structure "B-B". In column 6, lines 49-51, the Summerton patent refers to B-B as a carbamate-linked structure, not an amide-linked structure.

In the outstanding Office Action, the Examiner alleges that the carbamate (*i.e.*, -O-C(=O)-NR-) linkage disclosed in the Summerton patent is anticipatory because: (1) Applicants' claims refer to compounds "containing neutral amide backbone linkages" and (2) the carbamate backbone linkage is one "viewed as containing amide" (Office Action dated August 28, 2009, at page 7). Applicants note, however, that the pending claims are not directed to compounds that (as in the Summerton patent) contain backbone linkages that, in turn, "contain amide." Rather, the claims are directed to compounds that "contain[] neutral amide backbone linkages."

Because the structure that the Summerton patent discloses is different from that recited in the instant claims, the rejection for alleged anticipation is improper and should be withdrawn.

#### ***Alleged Obviousness***

Claims 34-36, 38-41, 43-45, and 47-73 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,472,209 ("the Richelson patent"). This rejection is said to be based upon an assumption the instant claims are not entitled to the filing date of Application Serial No. 08/109591. Since, as noted above, this assumption is incorrect, Applicants request that the rejection for alleged obviousness be reconsidered and withdrawn.

#### ***Applicability of the Summerton Patent to the Richelson Patent Claims***

The Examiner has observed that a number of the pending claims are directed to substantially the same subject matter claimed in the Richelson patent (Office Action at page 7). The Patent Office thus appears to be of the view that the disclosure of the Summerton patent is as relevant to the Richelson patent claims as it is to Applicants' patent claims. As such the Summerton patent constitutes prior art to the Richelson patent under at least 35 U.S.C. § 102(b).

It therefore follows that should the Patent Office maintain the rejection for alleged anticipation of the instant claims in view of the Summerton patent, it is incumbent on the examiner to promptly prepare and file a memorandum setting forth these facts and submit such memorandum to the attention of the Office of Patent Legal Administration as is set forth

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**PATENT**

in section 2239 of the M.P.E.P. Further the Office of the Deputy Commissioner for Patent Examination Policy is requested to confirm that it has institute a Reexamination Ordered at the Director's Initiative under 37 CFR 1.520 of the Richelson patent claims.

***Conclusion***

Applicants believe the foregoing constitutes a complete response to the Office Action and submit that all pending claims are in condition for ready allowance. An early Office Action to that effect is, therefore, earnestly solicited.

Respectfully submitted,

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/Joseph Lucci/

Joseph Lucci

Registration No. 33,307

Woodcock Washburn LLP  
Cira Centre  
2929 Arch Street, 12th Floor  
Philadelphia, PA 19104-2891  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439